

**REMARKS**

Review and reconsideration on the merits are requested.

**Request for Telephone Interview**

A telephone interview is requested concerning the priority document and support for claim 1 therein. See the later discussion on this point.

**Formalities**

Applicants appreciate the Examiner acknowledging receipt of the certified copies of the priority documents from the International Bureau (there is one priority document) and returning initialed PTO/SB/08 which was filed with this application on September 29, 2005.

Applicants now address the rejections/objections in the order posed.

**Claim Rejections - 35 U.S.C. § 101**

Claims 19-22 and 26 are canceled.

**Claim Objections**

Claims 7-12, 14 and 24 are cancelled.

**Claim Rejections - 35 U.S.C. § 112**

**First Paragraph**

The phrase “prevention or” is canceled from claims 16-17. Claim 20 has already been canceled.

**Second Paragraph**

Of claims 15-22 and 25-26, all of these claims have earlier been canceled except for claims 15-18. Claim 17 depends from claim 16. Claim 25 depends from claim 15.

Claims 15, 16 and 18 are amended by reciting “to a patient in need thereof” after “administering”.

Withdrawal of all rejections/objections is requested.

**Claim Rejections - 35 U.S.C. § 102**

Claims 1, 3-4 and 6-26 were rejected under 35 U.S.C. § 102(e) as anticipated by US 7,129,220 B2 to Beavers et al (Beavers).

The present application claims a priority date of March 31, 2003, based on Japanese Application No. 97152/2003.

Of the rejected claims, only the following claims remain pending and only these claims will be treated in the attached certified translation of Applicants’ priority document:

Claims 1, 3, 4, 6, 13, 15-18, 23, 25 and, for completeness of response, new claim 28.

With respect to claim 28, many of the Example compounds are directed to the situation wherein Y is -O- or -S-. These provide support for new claim 28. The following Examples are particularly relevant: 1-10, 12-46 and 48-65 (disclosed in the present application and the priority document) and Examples 66-102 (disclosed only in the present application).

Even if Beavers is assumed to be entitled to an effective date of August 1, 2003, under 35 U.S.C. § 102(e) this is still later than Applicants’ claimed priority date of March 31, 2003.

Support for the indicated claims herein occurs in the certified translation as follows. Applicants give the number of the claim herein and then after the indication of support refer to the certified translation.

Claim 1 of the present application generally finds support in the certified translation of the priority document at [claim 1] which begins at page 1 and continues over to the first two lines

on page 8 and at page 18, the last line, [1] over to the first three lines on page 26, **with the following exceptions.**

The Examiner will note there is attached a copy of pages 2-8 of the PRELIMINARY AMENDMENT filed with this application entitled in the upper right hand corner FOR REFERENCE ONLY.

At various points, claim 1 in the present application uses C<sub>3-7</sub> whereas the priority document uses C<sub>3-8</sub>, i.e., the priority document is slightly broader.

Applicants would propose to leave claim 1 at this point using C<sub>3-7</sub> and rely upon the priority document in light of decisions such as *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Blaser*, 556 F.2d 534, 194 USPQ 122 (CCPA 1977) and *McLaughlin v. Roberts*, 197 USPQ 831 (Brd. of Pat. App. and Int. 1978), where disclosure of a slightly broader range in an earlier application was held to be a written description sufficient to support a slightly narrower range in a later application.

The points where the present application differs from the priority document have the numeral 8 over the numeral 7 in the attached PRELIMINARY AMENDMENT.

At various points, claim 1 uses C<sub>2-7</sub> whereas the priority document uses C<sub>2-6</sub>, i.e., the priority document is slightly narrower. Applicants incorporated by reference the entire disclosure of the priority document in the documents filing this application. They would propose to amend C<sub>2-7</sub> to C<sub>2-6</sub> in claim 1 based on the priority document.

The points where this occurs in the PRELIMINARY AMENDMENT have the numeral 6 over the numeral 7 in claim 1.

Finally, certain groups in claim 1 do not occur at the above points referenced in the certified translation.

Points in the priority document where this occurs have an encircled numeral 1.

At certain points a group is recited in the priority document but not in claim 1 of the present application. These points are indicated with an encircled numeral 2.

All of the points above are being checked with the Inventors.

Applicants further advise that the sulfamide group (-NH<sub>2</sub>SO<sub>2</sub>NH<sub>2</sub>) in R<sup>E</sup>, R<sup>F</sup> and R<sup>G</sup> in the priority document was amended to a sulfamoyl group (-SO<sub>2</sub>NH<sub>2</sub>) which was actually intended at the time of filing of the International Application.

With respect to the remaining claims, these find support in the certified translation of the priority document as follows.

<b>Claim in Present Application</b>	<b>Priority Document</b>
3	[Cl. 3] p. 8; [3] p. 26.
4	[Cl. 4], p. 8; [4] p. 26.
6	[Cl. 6], p. 8; [6] p. 26.
13	[Cl. 13], p. 9; [13] p. 27; [0168] & [0170] p. 115+.
15	[Cl. 9] p. 8/9; [9] p. 27; [0168] & [0170] p. 115+.
16	[Cl. 10] p. 9; [10] p. 27; [0168] & [0170] p. 115+.
17	[Cl. 11] p. 9; [11] p. 27; [0168] & [0170] p. 115+.
18	[Cl. 12] p. 9; [12] p. 27; [0168] & [0170] p. 115+.
23 <sup>*</sup>	[Cl. 15] p. 9+; [15] p. 27+.
25 <sup>*</sup>	[Cl. 15] p. 9+; [15] p. 27+; [0168] & [0170] p. 115+.
28	Examples earlier discussed.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

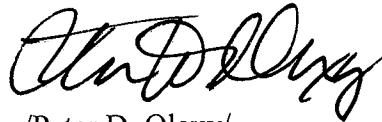
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<sup>\*</sup> Antidiarrhoics and cathartics do not seem to be disclosed.

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: January 2, 2008

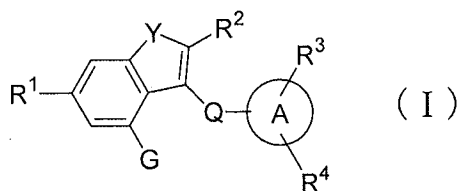
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**AMENDMENTS TO THE CLAIMS**

**This listing of claims will replace all prior versions and listings of claims in the application:**

**LISTING OF CLAIMS:**

1. ~~(currently amended)~~: A fused heterocyclic derivative represented by the following general formula (I):



wherein

R<sup>1</sup> represents a hydrogen atom, a halogen atom, a hydroxy group, an amino group, a mono or di(C<sub>1-6</sub> alkyl)amino group, a C<sub>1-6</sub> alkyl group, a C<sub>1-6</sub> alkoxy group, a halo(C<sub>1-6</sub> alkyl) group, a halo(C<sub>1-6</sub> alkoxy) group, a hydroxy(C<sub>1-6</sub> alkyl) group, a hydroxy(C<sub>1-6</sub> alkoxy) group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]amino group, a carboxy group, a C<sub>2-7</sub> alkoxy carbonyl group, a carbamoyl group or a carbamoyl(C<sub>1-6</sub> alkyl) group;

R<sup>2</sup> represents a hydrogen atom, a halogen atom or a C<sub>1-6</sub> alkyl group;

R<sup>3</sup> and R<sup>4</sup> independently represent a hydrogen atom, a hydroxy group, a halogen atom, a C<sub>1-6</sub> alkyl group, a C<sub>2-6</sub> alkenyl group, a C<sub>2-6</sub> alkynyl group, a C<sub>1-6</sub> alkoxy group, a C<sub>2-6</sub> alkenyloxy group, a C<sub>1-6</sub> alkylthio group, a C<sub>2-6</sub> alkenylthio group, a halo(C<sub>1-6</sub> alkyl) group, a halo(C<sub>1-6</sub> alkoxy) group, a halo(C<sub>1-6</sub> alkylthio) group, a hydroxy(C<sub>1-6</sub> alkyl) group, a hydroxy(C<sub>2-6</sub> alkenyl) group, a hydroxy(C<sub>1-6</sub> alkoxy) group, a hydroxy(C<sub>1-6</sub> alkylthio) group, a carboxy

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group, a carboxy(C<sub>1-6</sub> alkyl) group, a carboxy(C<sub>2-6</sub> alkenyl) group, a carboxy(C<sub>1-6</sub> alkoxy) group, a carboxy(C<sub>1-6</sub> alkylthio) group, a C<sub>2-7</sub> alkoxy carbonyl group, a C<sub>2-7</sub> alkoxy carbonyl-substituted (C<sub>1-6</sub> alkyl) group, a C<sub>2-7</sub> alkoxy carbonyl-substituted (C<sub>2-6</sub> alkenyl) group, a C<sub>2-7</sub> alkoxy carbonyl-substituted (C<sub>1-6</sub> alkoxy) group, a C<sub>2-7</sub> alkoxy carbonyl-substituted (C<sub>1-6</sub> alkylthio) group, a C<sub>1-6</sub> alkylsulfinyl group, a C<sub>1-6</sub> alkylsulfonyl group, -U-V-W-N(R<sup>5</sup>)-Z or any of the following substitutes (i) to (xxviii) which may have 1 to 3 substituents selected from the following substituent group  $\alpha$  on the ring;

(i) a C<sub>6-10</sub> aryl group, (ii) C<sub>6-10</sub> aryl-O-, (iii) C<sub>6-10</sub> aryl-S-, (iv) a C<sub>6-10</sub> aryl-substituted (C<sub>1-6</sub> alkyl) group, (v) a C<sub>6-10</sub> aryl-substituted (C<sub>1-6</sub> alkoxy) group, (vi) a C<sub>6-10</sub> aryl-substituted (C<sub>1-6</sub> alkylthio) group, (vii) a heteroaryl group, (viii) heteroaryl-O-, (ix) heteroaryl-S-, (x) a heteroaryl(C<sub>1-6</sub> alkyl) group, (xi) a heteroaryl(C<sub>1-6</sub> alkoxy) group, (xii) a heteroaryl(C<sub>1-6</sub> alkylthio) group, (xiii) a C<sub>3-7</sub><sup>8</sup> cycloalkyl group, (xiv) C<sub>3-7</sub><sup>8</sup> cycloalkyl-O-, (xv) C<sub>3-7</sub><sup>8</sup> cycloalkyl-S-, (xvi) a C<sub>3-7</sub><sup>8</sup> cycloalkyl-substituted (C<sub>1-6</sub> alkyl) group, (xvii) a C<sub>3-7</sub><sup>8</sup> cycloalkyl-substituted (C<sub>1-6</sub> alkoxy) group, (xviii) a C<sub>3-7</sub><sup>8</sup> cycloalkyl-substituted (C<sub>1-6</sub> alkylthio) group, (xix) a heterocycloalkyl group, (xx) heterocycloalkyl-O-, (xxi) heterocycloalkyl-S-, (xxii) a heterocycloalkyl(C<sub>1-6</sub> alkyl) group, (xxiii) a heterocycloalkyl(C<sub>1-6</sub> alkoxy) group, (xxiv) a heterocycloalkyl(C<sub>1-6</sub> alkylthio) group, (xxv) an aromatic cyclic amino group, (xxvi) an aromatic cyclic amino(C<sub>1-6</sub> alkyl) group or (xxvii) an aromatic cyclic amino(C<sub>1-6</sub> alkoxy) group, (xxviii) an aromatic cyclic amino(C<sub>1-6</sub> alkylthio) group,

U represents -O-, -S- or a single bond and with the proviso that at least one of V and W is not a single bond, when U is -O- or -S-;

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V represents a C<sub>1-6</sub> alkylene group which may have a hydroxy group, a C<sub>2-6</sub> alkenylene group or a single bond;

W represents -CO-, -SO<sub>2</sub>-, -C(=NH)- or a single bond;

Z represents a hydrogen atom, a C<sub>2-7</sub> alkoxy carbonyl group, a C<sub>6-10</sub> aryl-substituted (C<sub>2-7</sub> alkoxy carbonyl) group, a formyl group, -R<sup>A</sup>, -COR<sup>B</sup>, -SO<sub>2</sub>R<sup>B</sup>, -CON(R<sup>C</sup>)R<sup>D</sup>, -CSN(R<sup>C</sup>)R<sup>D</sup>, -SO<sub>2</sub>NHR<sup>A</sup> or -C(=NR<sup>E</sup>)N(R<sup>F</sup>)R<sup>G</sup>;

R<sup>S</sup>, R<sup>A</sup>, R<sup>C</sup> and R<sup>D</sup> independently represent a hydrogen atom, a C<sub>1-6</sub> alkyl group which may have 1 to 5 substituents selected from the following substituent group β or any of the following substitutes (xxix) to (xxxii) which may have 1 to 3 substituents selected from the following substituent group α;

(xxix) a C<sub>6-10</sub> aryl group, (xxx) a heteroaryl group, (xxxi) a C<sub>3-7</sub><sup>6</sup> cycloalkyl group or (xxxii) a heterocycloalkyl group

or both of Z and R<sup>S</sup> bind together with the neighboring nitrogen atom to form an aliphatic cyclic amino group which may have 1 to 3 substituents selected from the following substituent group α;

or both of R<sup>C</sup> and R<sup>D</sup> bind together with the neighboring nitrogen atom to form an aliphatic cyclic amino group which may have 1 to 3 substituents selected from the following substituent group α;

R<sup>B</sup> represents a C<sub>2-7</sub> alkoxy carbonyl group, a C<sub>1-6</sub> alkylsulfonylamino group, a C<sub>6-10</sub> arylsulfonylamino group, a C<sub>1-6</sub> alkyl group which may have 1 to 5 substituents selected from the



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following substituent group  $\beta$  or any of the following substitutes (xxxiii) to (xxxvi) which may have 1 to 3 substituents selected from the following substituent group  $\alpha$ ;

(xxxiii) a C<sub>6-10</sub> aryl group, (xxxiv) a heteroaryl group, (xxxv) a C<sub>3-7</sub> cycloalkyl group or (xxxvi) a heterocycloalkyl group,

R<sup>E</sup>, R<sup>F</sup> and R<sup>G</sup> independently represent a hydrogen atom, a cyano group, a carbamoyl group, a C<sub>2-7</sub> acyl group, a C<sub>2-7</sub> alkoxy carbonyl group, a C<sub>6-10</sub> aryl-substituted (C<sub>2-7</sub> alkoxy carbonyl) group, a nitro group, a C<sub>1-6</sub> alkylsulfonyl group, a <sup>Sulfamide</sup> sulfamoyl group, a carbamimidoyl group or a C<sub>1-6</sub> alkyl group which may have 1 to 5 substituents selected from the following substituent group  $\beta$ ;

or both of R<sup>E</sup> and R<sup>F</sup> bind together to form an ethylene group;

or both of R<sup>F</sup> and R<sup>G</sup> bind together with the neighboring nitrogen atom to form an aliphatic cyclic amino group which may have a substituent selected from the following substituent group  $\alpha$ ;

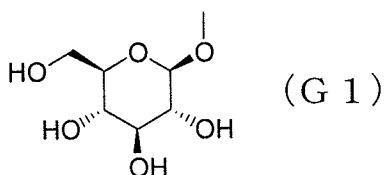
Y represents -O-, -S-, or -NH- which may be substituted by a C<sub>1-6</sub> alkyl group or a halo(C<sub>1-6</sub> alkyl) group;

Q represents -C<sub>1-6</sub> alkylene-, -C<sub>2-6</sub> alkenylene-, -C<sub>1-6</sub> alkylene-O-, -C<sub>1-6</sub> alkylene-S-, -O-C<sub>1-6</sub> alkylene-, -S-C<sub>1-6</sub> alkylene-, -C<sub>1-6</sub> alkylene-O-C<sub>1-6</sub> alkylene- or -C<sub>1-6</sub> alkylene-S-C<sub>1-6</sub> alkylene-;

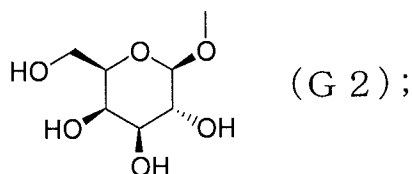
ring A represents a C<sub>6-10</sub> aryl group or a heteroaryl group;

G represents a group represented by the formula:

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or a formula:



[substituent group  $\alpha$ ]

a halogen atom, a hydroxy group, an amino group, a C<sub>1-6</sub> alkyl group, a C<sub>1-6</sub> alkoxy group, a halo(C<sub>1-6</sub> alkyl) group, a halo(C<sub>1-6</sub> alkoxy) group, a hydroxy(C<sub>1-6</sub> alkyl) group, a C<sub>2-7</sub> alkoxy carbonyl-substituted (C<sub>1-6</sub> alkyl) group, a hydroxy(C<sub>1-6</sub> alkoxy) group, an amino(C<sub>1-6</sub> alkyl) group, an amino(C<sub>1-6</sub> alkoxy) group, a mono or di(C<sub>1-6</sub> alkyl)amino group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]amino group, a C<sub>1-6</sub> alkylsulfonyl group, a C<sub>1-6</sub> alkylsulfonylamino group, a C<sub>1-6</sub> alkylsulfonylamino-substituted (C<sub>1-6</sub> alkyl) group, a carboxy group, a C<sub>2-7</sub> alkoxy carbonyl group, a sulfamoyl group and  $-\text{CON}(\text{R}^{\text{H}})\text{R}^{\text{I}}-\text{CON}(\text{R}^{\text{H}})\text{R}^{\text{I}}$

[substituent group  $\beta$ ]

a halogen atom, a hydroxy group, an amino group, a C<sub>1-6</sub> alkoxy group, a C<sub>1-6</sub> alkylthio group, a halo(C<sub>1-6</sub> alkoxy) group, a halo(C<sub>1-6</sub> alkylthio) group, a hydroxy(C<sub>1-6</sub> alkoxy) group, a hydroxy(C<sub>1-6</sub> alkylthio) group, an amino(C<sub>1-6</sub> alkoxy) group, an amino(C<sub>1-6</sub> alkylthio) group, a mono or di(C<sub>1-6</sub> alkyl)amino group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]amino group, an ureido group, a sulfamide group, a mono or di(C<sub>1-6</sub> alkyl)ureido group, a mono or di[hydroxy(C<sub>1-6</sub>

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alkyl)]ureido group, a mono or di(C<sub>1-6</sub> alkyl)sulfamide group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]-sulfamide group, a C<sub>2-7</sub> acylamino group, an amino(C<sub>2-7</sub> acylamino) group, a C<sub>1-6</sub> alkylsulfonyl group, a C<sub>1-6</sub> alkylsulfonylamino group, a carbamoyl(C<sub>1-6</sub> alkylsulfonylamino) group, a carboxy group, a C<sub>2-7</sub> alkoxy carbonyl group, -CON(R<sup>H</sup>)R<sup>I</sup>, and any of the following substitutes (xxxvii) to (xxxviii) which may have 1 to 3 substituents selected from the above substituent group  $\alpha$  on the ring;

(xxxvii) a C<sub>6-10</sub> aryl group, (xxxviii) C<sub>6-10</sub> aryl-O-, (xxxix) a C<sub>6-10</sub> aryl-substituted (C<sub>1-6</sub> alkoxy) group, (xxxx) a C<sub>6-10</sub> aryl-substituted (C<sub>1-6</sub> alkylthio) group, (xxxxi) a heteroaryl group, (xxxvii) heteroaryl-O-, (xxxviii) a C<sub>3-7</sub> cycloalkyl group, (xxxix) C<sub>3-7</sub> cycloalkyl-O-, (xxxv) a heterocycloalkyl group, (xxxvi) heterocycloalkyl-O-, (xxxvii) an aliphatic cyclic amino group or (xxxviii) an aromatic cyclic amino group

R<sup>H</sup> and R<sup>I</sup> independently represent a hydrogen atom or a C<sub>1-6</sub> alkyl group which may have 1 to 3 substituents selected from the following substituent group  $\gamma$ ;

or both of R<sup>H</sup> and R<sup>I</sup> bind together with the neighboring nitrogen atom to form an aliphatic cyclic amino group which may have 1 to 3 substituents selected from the following substituent group  $\delta$ ;

[substituent group  $\gamma$ ]

a halogen atom, a hydroxy group, an amino group, a C<sub>1-6</sub> alkoxy group, a halo(C<sub>1-6</sub> alkoxy) group, a hydroxy(C<sub>1-6</sub> alkoxy) group, an amino(C<sub>1-6</sub> alkoxy) group, a mono or di(C<sub>1-6</sub> alkyl)amino group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]amino group, an ureido group, a sulfamide group, a mono or di(C<sub>1-6</sub> alkyl)ureido group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]ureido group, a

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mono or di(C<sub>1-6</sub> alkyl)sulfamide group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]sulfamide group, a C<sub>2-7</sub><sup>6</sup> acylamino group, an amino(C<sub>2-7</sub> acylamino)<sup>6</sup> group, a C<sub>1-6</sub> alkylsulfonyl group, a C<sub>1-6</sub> alkylsulfonylamino group, a carbamoyl(C<sub>1-6</sub> alkylsulfonylamino) group, a carboxy group, a C<sub>2-7</sub> alkoxycarbonyl group<sup>②</sup> and -CON(R<sup>J</sup>)R<sup>K</sup>

[substituent group δ]

a halogen atom, a hydroxy group, an amino group, a C<sub>1-6</sub> alkyl group, a C<sub>1-6</sub> alkoxy group, a halo(C<sub>1-6</sub> alkyl) group, a halo(C<sub>1-6</sub> alkoxy) group, a hydroxy(C<sub>1-6</sub> alkyl) group, a C<sub>2-7</sub> alkoxycarbonyl-substituted (C<sub>1-6</sub> alkyl) group, a hydroxy(C<sub>1-6</sub> alkoxy) group, an amino(C<sub>1-6</sub> alkyl) group, an amino(C<sub>1-6</sub> alkoxy) group, a mono or di(C<sub>1-6</sub> alkyl)amino group, a mono or di[hydroxy(C<sub>1-6</sub> alkyl)]amino group, a C<sub>1-6</sub> alkylsulfonyl group, a C<sub>1-6</sub> alkylsulfonylamino group, a C<sub>1-6</sub> alkylsulfonylamino-substituted (C<sub>1-6</sub> alkyl) group, a carboxy group, a C<sub>2-7</sub> alkoxycarbonyl group, a sulfamoyl group and -CON(R<sup>J</sup>)R<sup>K</sup>

R<sup>J</sup> and R<sup>K</sup> independently represent a hydrogen atom or a C<sub>1-6</sub> alkyl group which may have any 1 to 3 substituents selected from a hydroxy group, an amino group, a mono or di(C<sub>1-6</sub> alkyl)amino group, a C<sub>2-7</sub> alkoxycarbonyl group<sup>①</sup> and a carbamoyl group;

or both of R<sup>J</sup> and R<sup>K</sup> bind together with the neighboring nitrogen atom to form an aliphatic cyclic amino group which may have any 1 to 3 substituents selected from a hydroxy group, an amino group, a mono or di(C<sub>1-6</sub> alkyl)amino group, a C<sub>1-6</sub> alkyl group, a hydroxy(C<sub>1-6</sub> alkyl) group, a C<sub>2-7</sub> alkoxycarbonyl group<sup>①</sup>, a C<sub>2-7</sub> alkoxycarbonyl-substituted (C<sub>1-6</sub> alkyl) group<sup>①</sup> and a carbamoyl group,

or a pharmaceutically acceptable salt thereof, or a prodrug thereof.